Specification

Be It Known That I, **NAISHU WANG** a citizen of the United States of America, resident of San Diego, County of San Diego, State of California, have invented a new and useful

DISPOSABLE IMMUNOASSAY SAMPLE-COLLECTOR AND CHROMATOGRAPHIC-TESTING DEVICE

of which the following is a specification:

Field of the Invention

This invention relates to chromatographic immunoassay testing devices and more particularly to apparatuses for collecting a liquid sample and performing concurrent multiple tests by contact with chromatographic strips.

Background of the Invention

The collection of fluid specimens such as blood, saliva and urine and the conduct of immunoassay tests on such specimens to detect the presence or absence of certain chemicals, hormones, antibodies or antigens by dipping into the fluid specimen chromatographic testing strips requires a great deal of manipulation involving risks of contamination, mishandling, mislabeling and even complete loss of the specimen through spilling. Lack of consistency in the volume and pressure conditions of each test can affect the results and distort statistical data gathered from multiplicity of tests. Proper or equal dosage of the specimen, pretesting for adulterating additions further increase the risk of mishandling, contamination and loss. Further, fecal material suspended in a fluid wash buffer, and fluids such as saliva previously diluted in a mouthwash such as a phosphate buffer saliva (PBS) solution would be placed in a separate container prior to testing for hepatitis, HIV and other pathogens, or pathogenic antigens.

This invention results from an attempt to devise a simple, multi-use apparatus that minimizes handling of the specimen while expediting the whole procedure.

Summary of the Invention

The principal and secondary objects of this invention are to provide an apparatus for safely

and accurately conducting a number of immunoassay tests on a quantified amount of a liquid sample by exposure to a number of chromatographic strips while at the same time avoiding contamination or any loss of the sample through inadvertent spilling, in which the apparatus's simplicity and low manufacturing cost of the appartus allow it to be discarded after use.

These and other valuable objects are achieved by a liquid sample collector and polychromatice testing apparatus which comprises a sealable collection vessel associated and integrally formed with a number of testing stations in a single compact, simple, inexpensive and disposable package. A valve manipulable by a knob on the front of the apparatus simultaneously distributes metered amounts of the fluid specimen to a number of testing stations including an adulteration testing station. During pre-use storage and pre and post collection transportation of the apparatus, all the testing areas are exposed to a desiccant compound which is automatically removed before the testing strips are exposed to the test sample. Isobaric conditions are maintained through those testing areas by isometric configuration of all the specimen-carrying structures.

Brief Description of the Drawing

Figure 1 is a front and top perspective view of the apparatus according to the invention;

Figure 2 is a cutout view thereof exposing a portion of the valve mechanism;

Figure 3 is a perspective view of the valve body;

Figure 4 is a bottom plan view of the apparatus with the base pan removed; and

Figure 5 is a top plan view of the base pan.

Description of the Preferred Embodiment of the Invention

Referring now to the drawing, there is shown a disposable and one-time use apparatus **1** for collecting a liquid specimen and conducting a multiplicity of immunochromatographic tests on a metered amount of the specimen.

The apparatus comprises a cylindrical specimen-collecting vessel **2** covered by a self-snapping lid **3**, a hand-operable valve **4**, a base pan **5**, a pair of multi-strip test stations **6** mounted astride the vessel and valve, and an adulteration test station **7** along the frontal edge of the pan **5**. The valve **4** is located between the vessel **2** and the pan **5** under a semi-cylindrical tunnel **8** formed in the bottom piece **9** of the vessel. The valve comprises a cylindrical body **10** having an axis **X-X'** oriented horizontally under a median portion of the vessel **2**. The valve is supported by a hemi-cylindrical trough **11** which, with the tunnel portion **8** of the bottom piece, forms a cylindrical bearing **12** into which the cylindrical body **10** of the valve is journaled. An aperture **13** in the tunnel portion of the vessel's bottom piece **9** is controlled by the valve **4**.

As more specifically illustrated in Figure 3, the valve comprises a frontal knob **14** for manually controlling the axial rotation of the cylindrical body **10**. A lateral first cavity **15** in the cylindrical body of the valve is shaped, positioned and dimensioned to accept a metered amount of fluid specimen through the aperture **13** when, in a first position of the valve, the cavity **15** is lined up with the aperture **13**. When the valve is rotated 180 degees clockwise, the contents of the first cavity **15** is dumped into the underlying pan **5** through a dumping circular port **16** in the bottom of the trough **11**. A lateral second cavity **17** is formed into the distal portion of the cylindrical body **10** and positioned axially distant and diametrically opposite the first cavity **15**. The second cavity is shaped, dimensioned, and positioned to hold an amount of desiccant which

is exposed to the inside surfaces of the underlying pan **5** when the valve is in its first resting position through a second port **18** in the trough section **11**. When the valve is rotated to its second dumping position, the second cavity **17** is no longer lined up with the second port **18**, and the internal surfaces of the pan are no longer exposed to it.

It should be understood that other types of valve geometry could also be used. For instance, the valve can be of an axially translating type where the knob is held in its most recessed, distal position during storage and shipping. It can be pulled outwardly to an intermediary position where a measured amount of fluid specimen is accepted ito the valve body. Finally, when the knob is pulled in a third most outward position, the measured amount of specimen is dumped into the well **20** through appropriate openings.

As more specifically illustrated in Figure 5, the inside of the pan is divided by a series of walls **19** to form a cylindrical well **20** commensurate with, and located immediately below the specimen dumping port **16**. The well acts as a receiving station for the fluid specimen and is divided into two symmetrical portions **21, 22** each in communication with a passageway **23, 24** leading to the base of one of the testing stations **6**. The symmetricality of the well portions, and passageways provides for an isovolumetric and isobaric distribution of the fluid specimen to the pair of testing stations.

As more specifically illustrated in Figure 2, each of the two lateral testing stations **6** mounts a number of chromatographic testing strips **25** which extend all the way down into the portion of the pan underlying the test station. A pair of symmetrical channels **26** in the frontal portion of the pan diverts an equal amount of fluid specimen from each of the passageways **23, 24** and bring them to the adulteration testing station **7** in the frontal portion of the base pan **5**.

The symmetricality of the channels **26** preserves the isobaric conditions of the amount of fluid specimen send to the lateral testing stations.

The valve secured into the cylindrical housing **12** by the C-clip **27** engage through a slot **28** in the bottom of the housing and capturing a circular groove **29** in the cylindrical body of the valve between the proximal portion carrying the first cavity **15** and the distal portion carrying the second cavity **17**. Engaged into the same groove, is a spring-biased ratchet mechanism **30** which allows only uni-directional, clockwise rotation of the valve, and includes a barrier to prevent travel beyond the 180 degrees necessary to transport the fluid from the vessel to the receiving station in the pan. The external surface of the vessel's wall **31** extends over the lateral test stations **6, 7** to form an all-encompassing transparent shell which meets and is hermetically sealed, with the bottom edges of the pan **5**.

Accordingly, there is provided a sealable vessel for collecting an immunoassay liquid specimen that is integrally associated with multi-strip chromatographic testing stations wherein a metered amount of the fluid specimen can be conveniently transported by manipulation of the valve knob to the base pan **5** for distribution to the stations. The pan, valve housing and station walls form a closed chamber which prior to the manipulation of the valve, is exposed to the desiccant to prevent accumulation of moisture into the test station during the storage, and pre and post collection transportation of the apparatus.

While the preferred embodiment of the invention has been described, modifications can be made and other embodiments may be devised without departing from the spirit of the invention and the scope of the appended claims.

WHAT IS CLAIMED IS: